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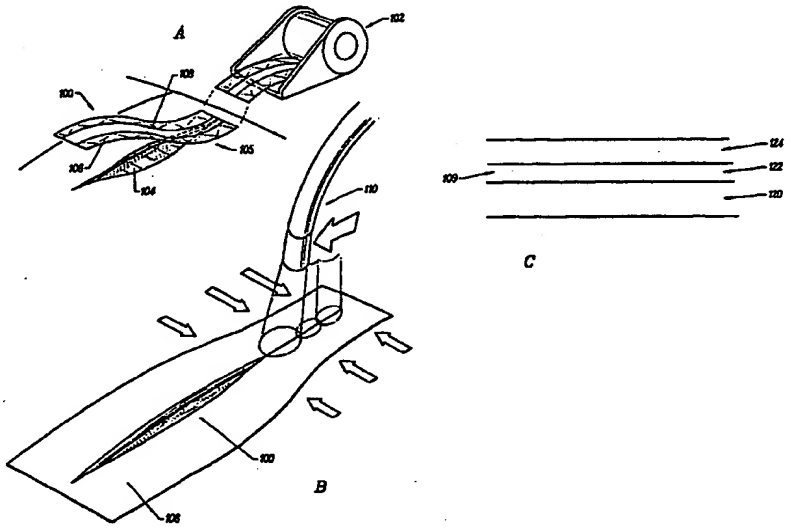

(57) Abstract

A wound closure strip provides inward tension on the skin from both sides of an incision or wound. The tension is communicated to the skin through the action of an adhesive. Tension is applied by disposing a uniaxially oriented rectangular film or an elastic film support member of the closure strip across the incision. The film then relaxes back to a predefined size (length and width). If the length to width ratio is small, a biaxially oriented film, such as a shrink wrap film, may be used, which is caused to relax to provide the desired force and inward tension across the wound or incision. The wound closure strip may also be a wound healing patch which includes an adhesive trail positioned on a side of the patch that makes contact with the skin. The adhesive trail can be customized or applied so that substantially none of the adhesive covers the wound. Instead, the adhesive trail is positioned adjacent to the wound. The adhesive trail can be activated by a variety of different methods including but not limited to light and pressure.

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WOUND CLOSURE STRIPS

CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority to the U.S. provisional application entitled CLOSURE STRIP, Serial No. 60/033,117, filed December 18, 1996, and invented by Theodore L. Parker, Ronald Lax, Thomas C. Wehman, and T. Christian Wehman, and the U.S. provisional application entitled IRREGULAR WOUND CLOSURE SHEET, Serial No. 60/033,198, filed December 18, 1996, and invented by Theodore L. Parker and Thomas C. Wehman.

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to a wound closure patch, and more particularly to a wound closure strip that provides inward tension on the skin from both sides of an incision or wound.

Description of the Related Art

Often it is necessary to very quickly stop bleeding from an artery during surgery as well as other times when the artery has been nicked. One method of stopping blood flow from the artery is to apply pressure directly to the artery with the use of one's finger.

Mechanical devices for effecting non-invasive compression of arteries include the use of pressure cuffs. Typically, the cuff includes a strip of non-elastic material to be wrapped around a limb. An elastic inflatable bladder is superimposed on the non-elastic material. When the bladder is inflated pressure exerted by all parts of the enwrapment on the limb is increased. U.S. Patent No. 3,171,410 discloses a pneumatic dressing which exemplifies traditional pressure cuff devices.

Other mechanical devices have been used for decades to achieve hemostasis. Many of these have been based on a C- or U-shaped clamp that use a ratcheting effect to allow the operator to apply or release pressure to the puncture site. These clamps have proven to be efficient alternatives to manual compression for control of bleeding after the removal of transfemoral sheaths.

One C-clamp device features a rigid footplate, as disclosed in U.S. Patent No. 3,799,249 (hereafter the '249 patent). The apparatus of the '249 patent is used to exert non-calibrated and unevenly distributed pressure to the body surface overlying an artery. The use of C-clamps can also cause hematomas and they can only be used for a limited time.

U.S. Patent No. 3,625,219 discloses a transparent rubber membrane clamped to a transparent plastic plate to form an expandable pressure chamber. Clamping screws are used to maintain various members of the chamber support structure in place, and must be loosened to adjust the position of the chamber relative the area to which pressure is to applied.

Further, another type of mechanical device is disclosed in U.S. Patent Number 4,233,980 (hereafter the '980 patent). In the '980 patent, an inflatable bladder is formed with two sheets of transparent, non-elastic material that provide lateral restraint. The bladder is inflated by the introduction of a fluid. Vertical expansion is accomplished by the separation of the two sheets of material due to inflation. The bladder is typically mounted on a pressure plate. The pressure plate is mounted on a positioning arm.

Pressure-sensitive adhesives (hereafter PSAs) are used for a variety of industrial, consumer, and medical applications. PSAs are characterized as being normally tacky and exhibit instant tack when applied to a substrate. A variety of polymers have been used to manufacture PSAs, for example acrylic and methacrylic ester homo- or copolymers, butyl rubber-based systems, silicones, urethanes, vinyl esters and amides, olefin copolymer materials, natural or synthetic rubbers, and the like.

Flexible polymeric film materials are also known such as described in European Patent Application Nos. 0107915 and 0147119 and

PCT/GB91/00496, all of which are incorporated herein by reference, to disclose materials with particular moisture vapor transmission rates which might be used as backing materials in connection with the certain aspects of the present invention. Film materials which have moisture vapor transmission rates generally compatible with human skin are most preferred.

S.C. Temin, Encyclopedia of Polymer Science and Engineering, Vol. 13, at 345-68 (1988), and Handbook of Pressure-Sensitive Adhesive Technology (Donates Satas ed., 1982) both provide a comprehensive overview of medical and other adhesives, and are incorporated herein by reference.

A PCT publication WO91/14462, published October 3, 1991, refers to medical devices comprised of a substrate with a particular moisture vapor transmission rate with an adhesive thereon which is tacky at skin temperature but less tacky or not tacky at room temperature. A similar medical adhesive device is disclosed in WO91/14461. The disclosure of both of these PCT publications is incorporated herein by reference to the extent they disclose such devices including particular backing layers, adhesives, and methods of use and manufacture.

The level of scarring resulting from a wound or surgical incision can be reduced by minimizing the outward (opening) tension on the wound during the so-called proliferative phase of healing beginning about 3-4 days after injury. Some specific factors, such as Vitamins C, A, and E, have also been suggested to reduce scarring. During granulation and continuing through wound contraction, collagen bundles appear and grow. Scar collagen is slowly densified by breakdown and reforming in a differentiation phase, which begins about day 21 and can continue for weeks or months. Possibly, an oriented templating surface for alignment of the collagen bundles across the wound opening could be included. This would provide increased strength and possibly reduce excess scarring.

It would be desirable to provide a wound healing patch suitable for irregular wounds. It would be further desirable to provide a wound healing patch which provides selective adherence of the patch to the skin.

SUMMARY OF THE INVENTION

An object of the present invention is to provide a wound closure device.

Another object of the present invention is to provide a wound closure device that provides inward tension on the skin from both sides of an incision or wound where the tension is communicated to the skin through the action of an adhesive.

One other object of the present invention is to provide a wound closure patch with a mechanical linkage to the skin that is used to provide tension on the skin around an incision or wound.

Yet another object of the present invention is to provide a wound closure device with a uniaxially oriented rectangular film which is applied across an incision and is configured to relax back to a predefined size.

Still a further object of the present invention is to provide a wound closure device made at least partially of an elastic film support member closure strip.

One more object of the invention is to provide a wound healing patch which provides for selective adherence to the skin at areas adjacent to an irregularly shaped wound.

These and other objects of the invention are achieved in a wound closure strip that provides inward tension on the skin from both sides of an incision or wound. The tension is communicated to the skin through the action of an adhesive. Tension is applied by disposing a uniaxially oriented rectangular film or an elastic film support member of the closure strip across the incision. The film then relaxes back to a predefined size (length and width). If the length to width ratio is high, preferably > 1, a biaxially oriented film, such as a shrink wrap film, may be used, which is caused to relax to provide the desired force and inward tension across the wound or incision.

An adhesive trail may also be positioned on a side of the patch that makes contact with the skin. The adhesive trail can be customized or applied so that substantially none of the adhesive covers the wound. Instead, the adhesive

trail is positioned adjacent to the wound. The adhesive trail can be activated by a variety of different methods including but not limited to light and pressure.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1A is a perspective view of the wound closure strip of the present invention.

FIG. 1B is a perspective view of a light wand supplying energy to the wound closure strip of the present invention to activate the wound closure strip, with the wound closure strip closing along the illustrated alignment lines.

FIG. 1C is a side view of the layers of the closure strip.

FIG. 2A is a perspective view of an irregular wound and the wound healing patch of the present invention.

FIG. 2B illustrates closure of a wound with the wound healing patch of the present invention.

FIG. 2C is another illustration of a wound with the wound healing patch of the present invention.

FIG. 2D illustrates the removal of the wound healing patch of the present invention.

DETAILED DESCRIPTION

The present invention includes a closure strip providing inward tension on the skin from both sides of an incision or wound, the tension being communicated to the skin through the action of an adhesive. Optionally, a mechanical linkage to the skin is used in addition to or in place of the adhesive, such as a triangular (pointed) mechanical clip or flat formed from a stiffer intermediate layer by a punch during manufacture. The triangular "hole" remaining, comprised of two cut sides and one side still attached to the backing film, increases air and water vapor exchange. Included is a compact area which contains specific healing medications in a moist medium dressing. The triangular flaps increase friction against the skin, but do not break the skin; flat size can be in the range of 0.25 mm - 1 mm.

Tension may be applied by disposing a uniaxially oriented rectangular film or an elastic film support member of the closure strip across the incision, then causing the oriented film to relax back to a predefined size (length and width). If the length to width ratio is high, preferably > 1, a biaxially oriented film, such as a shrink wrap film, may be used, which is caused to relax to provide the desired force and inward tension across the wound or incision.

In the case of a "circular" wound, a round biaxially oriented support is used.

To create the inward tension across the incision, the oriented film is relaxed; ultimately, the film returns to its pre-oriented size and geometry. Because the oriented film "remembers" its initial state, closure strips designed to shrink by a prescribed amount can be provided. This can be achieved with the use of shrink wrap tubing, where a 2:1, 2.5:1, etc. shrink ratio is specified. For example, a 1 inch diameter shrink tube specified as a 2:1 material will shrink to precisely 0.5 inches diameter after it is relaxed.

A method for relaxing the oriented film, tube, etc., is by the use of heat applied to the material. While some oriented film materials, such as nylon, PVDF (polyvinylidene fluoride), and Kynar require temperatures of 250-350 °F, which may be detrimental in most medical applications, other materials can be relaxed at suitable temperatures. Preferred materials include certain polyethylene oriented films, such as Raychem CGPE-105, Cryolite D-940 (W.R. Grace), and PVC (polyvinyl chloride), materials that may be relaxed at much lower temperatures in the range of 185-210 °F, in very short times, on the order of seconds. Protection of the patient's skin is reasonably provided by the wound dressing or a flexible foam layer during the short period of heating.

In one embodiment of the invention, the heat is provided from a exothermic chemical reaction or an exothermic heat of solvation. An example of the former is the process of hyper-corrosion, in which a dry mixture of materials capable of entering into an exothermic oxidation-reduction couple are contacted with water to serve as the initial electrolyte. An example of the latter is water

solvation of certain anhydrous salts, for example certain calcium salts which have large exothermic heats of solvation, specifically, heats of hydration.

In another embodiment, the heat is supplied by directed electromagnetic radiation in the wavelength range 1.0-10.0 microns onto the film to be relaxed. Ideally, the major energy output of the irradiator is at a wavelength that predominantly overlaps the absorption maximum of the oriented film in that wavelength region. Thus, a more preferred wavelength for irradiation is 3.0-6.5 microns. Such electromagnetic radiation is in the infrared portion of the spectrum. Quartz and ceramic resistive components are capable of such output when electric current of a specific voltage is applied. Generally, commercial resistive components designed to be used at 1000-1200 watts may be run at 300-400 watts to shift their output from the wavelengths commonly perceived as "heat" to the 3.0-5.0 micron wavelength region.

A further embodiment is a design where the dry, solid, hyper-corrodible component is held in a rectangular pouch prepared from the oriented polymer film by a process such as heat sealing. When the hyper-corrodible component is contacted with water, the exothermic reaction between components is contained within the pouch and the heat, being generated internally to the oriented film, is more efficiently utilized. Another embodiment is where the water is also held within the pouch with the dry corrodible component, but in its own capsule or ampule. Upon breakage of the capsule, the water is released, heat is evolved and the closure strip assembly shrinks across the wound or incision.

An alternative relaxation method can be the treatment of the oriented film construction with an evaporative plasticizing agent; candidate agents are ethyl alcohol, IPA, and acetone. Essentially, the strip shrinks due to the agent, which then evaporates and increases stiffness again.

Referring now to FIGURE 1A, a wound closure strip 100 of the present invention cut off a rolled dispenser 102. Wound closure strip 100 contains alignment marks 104. The distance between alignment marks 104 on wound closure strip 100 can be obtained in widths of 1 mm, 2 mm, 3 mm, etc., and are available for a surgeon to align the marks of the wound or incision at a wound

site 105 upon command. Commands can be from either a chemical, heat, or pressure, causing the alignment marks to close and align. An adhesive 106 is placed on either side of alignment marks 104. Between alignment marks 104 there is no adhesive 106, but a shrinkable material 108 that draws the wound or incision together. Adhesive 106 can either be adhesive typically found on a BAND-AID™ brand bandage, or can be a releasable adhesive mixture which is tenacious in the presence of water or blood, and may contain a detackifying agent in order to remove the strip when necessary. The detackifying agent is activated by heat, cold, intense light, or a chemical reagent.

Referring to FIGURE 1B, an example of an activating force to cause wound closure strip 100 to close along alignment marks 104, is shown. A light wand 110 is used to activate wound closure strip 100. FIGURE 1B shows the inward force of the closing as wound closure strip 100 is activated, and shows the non-closed wound or incision as wound closure strip 100 is being activated by light wand 110.

Adhesive 106 is of the same type as adhesive as described above, and adheres until commanded to release by way of heat, cold, intense light, or a chemical reagent. Wound closure strip 100 is removed by an intense light source, which causes adhesive 106 to harden and detackify. Another embodiment uses a chemical reagent like EDTA (ethylenediamine tetraacetic acid), or a solution of calciumides or sodiumides to cause adhesive 106 to lose its adhesive properties.

A shrinkable material 108 is in between the two alignment lines that shrinks upon command. The commands may be heat, cold, intense light, or chemicals such as a solvent or reagent solution. In order to activate the heat, there is a chemical reaction that takes place in proximity to wound closure strip 100 that can be activated by either reagent, solvent, or pressure.

FIGURE 1C is a side view of the layers of wound closure strip 100. At the bottom is an adhesive layer 120. On the top is a protective layer 124 which serves as a conduit for air, protects the wound from particulates, and protects the adhesive. The middle layer is an active layer 122, which is composed of

shrinkable material 108 and an activator 109. Activator 109 can be a microencapsulated hyper-corrodible material that generates heat on command for shrinkable material 108 that is heat activated. In another embodiment, shrinkable material 108 can be chemically activated, and activator 109 is a microencapsulated series of chemical reagents. In an alternative embodiment, wound closure strip 100 may also have a stiffener layer between any of the layers or on top of the protective layer. Stiffener layer limits the closure force and provides tissue edge alignment.

The non-adhesive area allows the wound or puncture to breathe. A transparent adhesive strip is disposed over the wound. The cover is gas permeable and offers some protection to the wound by filtering bacteria, as well as serve as a conduit for air to promote healing. An antiseptic or antibiotic healing enhancer can be impregnated into the second layer of the adhesive strip.

FIGURE 2A is a perspective view of another embodiment of a semi-porous wound closure sheet 200 of the present invention. Wound closure sheet 200 is shown covering an irregular wound 202.

In one embodiment, the entire wound closure sheet 200 is permeable. In another embodiment, the wound closure sheet 200 is only partially permeable. Wound closure sheet 200 is made of a biopolymer typically used in medical applications for wound dressings.

Adhesive trails 206 in wound closure sheet 200 are activated by an activating agent. The activating agent may be heat, a light wand, an infrared wand, cold, or a reagent. By way of example, FIGURE 2A shows a light wand 204, which can be a waveguide, outlining either side of wound 202 to activate adhesive trails 206 and set adhesive 106 on both sides of wound 202. Alternatively, adhesive trails 206 can be activated by pressure outlining alongside wound 202, which sets adhesive 106.

Adhesive trails 206 must be activated on each side of wound 202. The purpose of adhesive trails 206 is to obtain adherence of wound closure sheet 200 to the tissue. Only a portion of wound closure sheet 200 must be activated and be adherent. Wound closure sheet 200 is one universal size, due to the variety of

wound sizes. Wound closure sheet 200 can adhere to tissue without activation, but not very well.

FIGURE 2B shows closure initiated between the activated adhesive trails 206. A closure wand 210 of a different electromagnetic frequency than light wand 204 has the objective of setting a closure motion in place. Closure wand 210 scans along wound 202 between adhesive trails 206. This then shrinks the material together in wound closure sheet 200 and thus close and seal wound 202. Adhesive trails 206 are shown which were made from prior light wand 204.

FIGURE 2C is a more detailed drawing of the closure of wound 202 itself. An oriented backing layer 226 serves the purpose of holding and protecting against premature closure. Oriented backing layer 226 is the top part of wound closure sheet 200. An adhesive layer 220 is on the opposite side of wound closure sheet 200, and has mild adhesive properties along the entire surface. When an activating agent penetrates through to certain areas of adhesive layer 220, the activating agent activates a much stronger adhesive material. A microencapsulated reaction layer 224 activates adhesive layer 220. A force directing layer 222 orients force in different directions for closure. Due to the irregular nature of layer force directing layer 222, it can be aligned in several different ways.

Referring to FIGURE 2D, after wound 202 is healed and closed, wound closure sheet 200 can be removed by use of a swabbing agent 230. Swabbing agent 230 is moved along the adhesive areas and adhesive trails 206, causing wound closure sheet 200 to release from wound 202.

The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this art.

What is claimed is:

CLAIMS

1. A closure strip for closing a wound at a wound site, comprising:

an adhesive layer configured to be placed over a wound site, the adhesive layer including a non-adhesive area and an adhesive area, the non-adhesive area configured to be placed over the wound and the adhesive area configured to be placed at a periphery of the wound;

an active layer coupled to the adhesive layer, the active layer including a shrinkable material and an activator, the shrinkable material configured to shrink and apply a closure force to the wound when the activator is activated; and

a protective layer coupled to the active layer, the protective layer being gas permeable and allowing the wound to breathe.

2. The closure strip of claim 1, wherein the adhesive layer includes alignment marks to facilitate proper positioning of the closure strip.

3. The closure strip of claim 1, wherein the adhesive area contains a pressure sensitive adhesive.

4. The closure strip of claim 1, wherein the active layer includes an antiseptic.

5. The closure strip of claim 1, wherein the active layer includes an antibiotic healing enhancer.

6. The closure strip of claim 1, wherein the adhesive area contains a releasable adhesive mixture containing a detackifying agent.

7. The closure strip of claim 6, wherein the detackifying agent is activated by heat.

8. The closure strip of claim 6, wherein the detackifying agent is activated by cold.

9. The closure strip of claim 6, wherein the detackifying agent is activated by intense light.

10. The closure strip of claim 6, wherein the detackifying agent is activated by chemical reagents.

11. The closure strip of claim 10, wherein the chemical reagents include EDTA.

12. The closure strip of claim 10, wherein the chemical reagents include a solution of calciumides.

13. The closure strip of claim 10, wherein the chemical reagents include a solution of sodiumides.

14. The closure strip of claim 1, wherein the shrinkable material is activated by heat.

15. The closure strip of claim 1, wherein the shrinkable material is activated by cold.

16. The closure strip of claim 1, wherein the shrinkable material is activated by intense light.

17. The closure strip of claim 1, wherein the shrinkable material is activated by chemical reagents.

18. The closure strip of claim 1, wherein the activator is a microencapsulated hyper-corrodible material that is capable of generating heat.

19. The closure strip of claim 1, wherein the activator is a microencapsulated series of chemical reagents.

20. The closure strip of claim 1, further comprising a stiffener layer coupled to the active layer and configured to limit the closure force.

21. A wound closure sheet for closing a wound, comprising:

an adhesive layer having a non-activated state and an activated state, the adhesive layer having mild adhesive properties in the non-activated state and strong adhesive properties in the activated state;

a force directing layer coupled to the adhesive layer, the force directing layer capable of creating a force to close the wound when the force directing layer is exposed to a closure activating agent;

a microencapsulated reaction layer coupled to the adhesive layer, the microencapsulated reaction layer capable of causing at least a portion of the adhesive layer to transform from the non-activated state to the activated state when the microencapsulated reaction layer is exposed to an adhesive activating agent; and

an oriented backing layer coupled to the microencapsulated reaction layer.

22. The wound closure sheet of claim 21, wherein the closure activating agent is heat.

23. The wound closure sheet of claim 21, wherein the closure activating agent is intense light.

24. The wound closure sheet of claim 21, wherein the closure activating agent is infrared.

25. The wound closure sheet of claim 21, wherein the closure activating agent is cold.

26. The wound closure sheet of claim 21, wherein the closure activating agent is a reagent.

27. The wound closure sheet of claim 21, wherein the adhesive activating agent is heat.

28. The wound closure sheet of claim 21, wherein the adhesive activating agent is intense light.

29. The wound closure sheet of claim 21, wherein the adhesive activating agent is infrared radiation.

30. The wound closure sheet of claim 21, wherein the adhesive activating agent is cold.

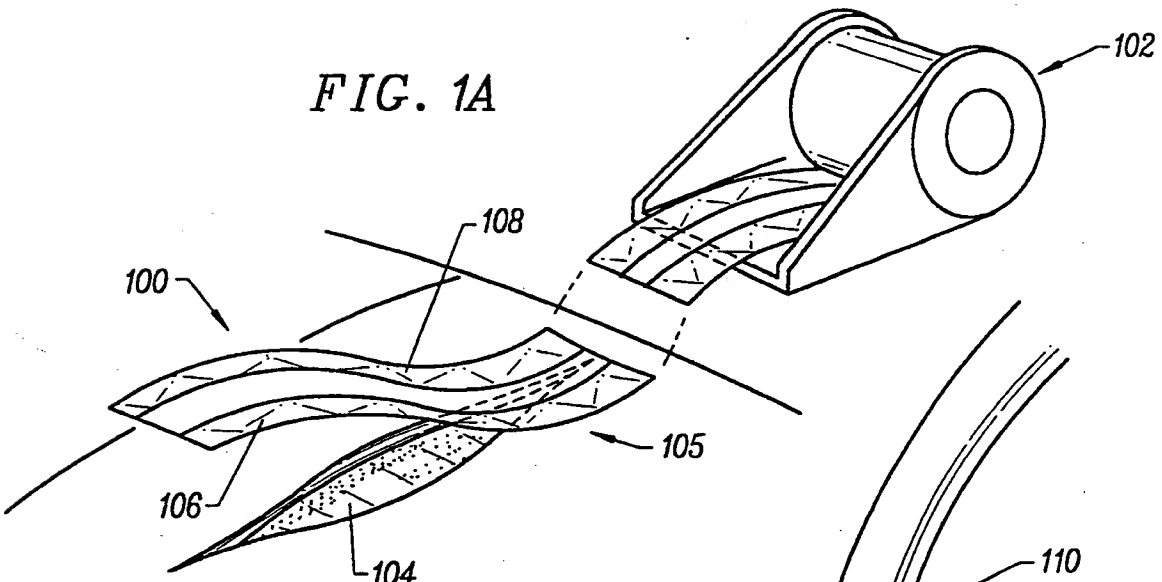
31. The wound closure sheet of claim 21, wherein the adhesive activating agent is a reagent.

32. The wound closure sheet of claim 21, wherein the adhesive layer in the activated state can be removed by application of a swabbing agent.

33. The wound closure sheet of claim 21, wherein the oriented backing layer is an uniaxially oriented film.

34. The wound closure sheet of claim 21, wherein the oriented backing layer is a biaxially oriented film.

FIG. 1A



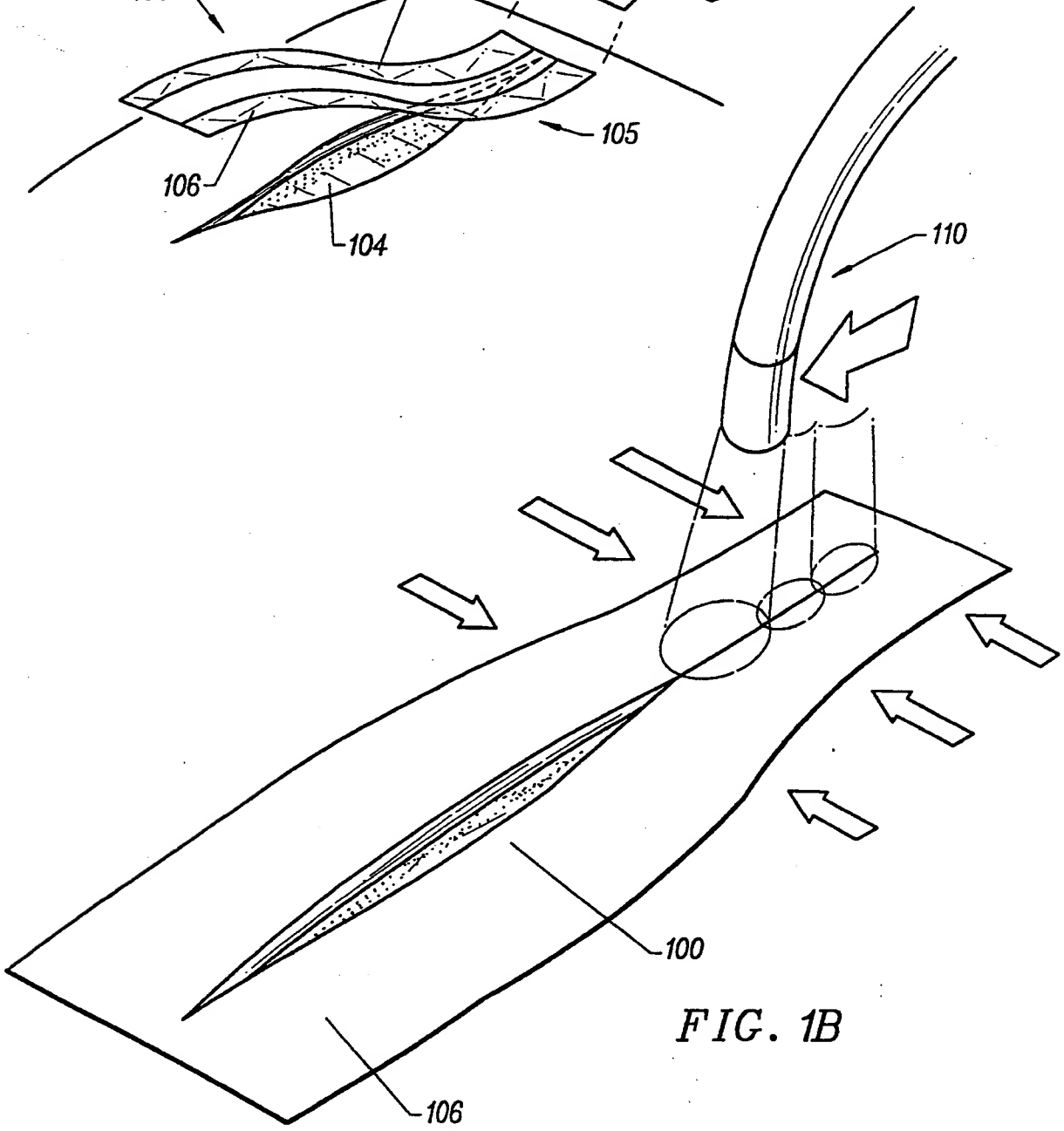


FIG. 1B

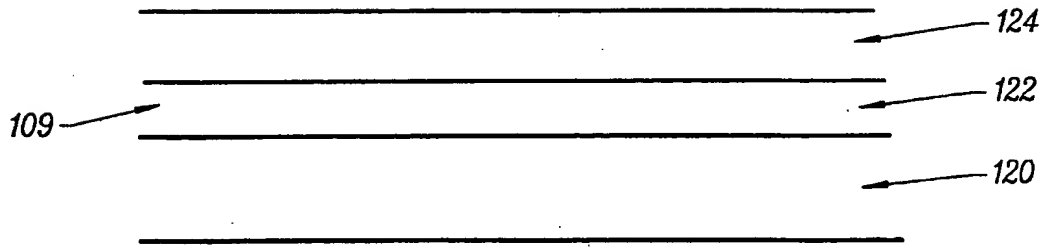


FIG. 1C

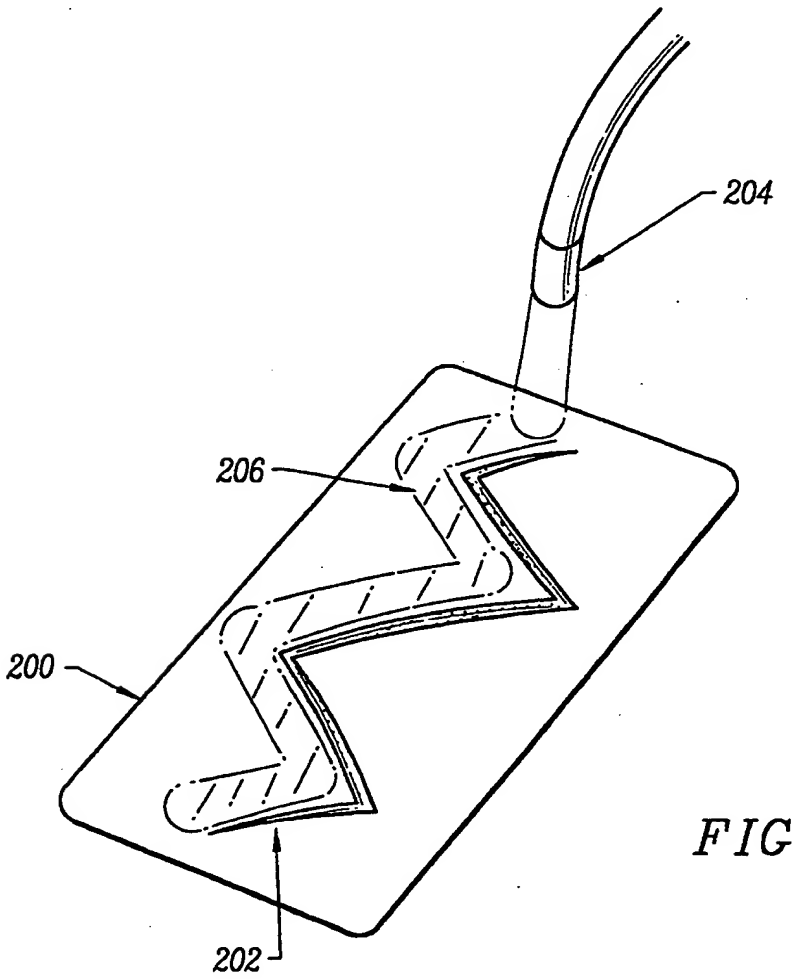


FIG. 2A

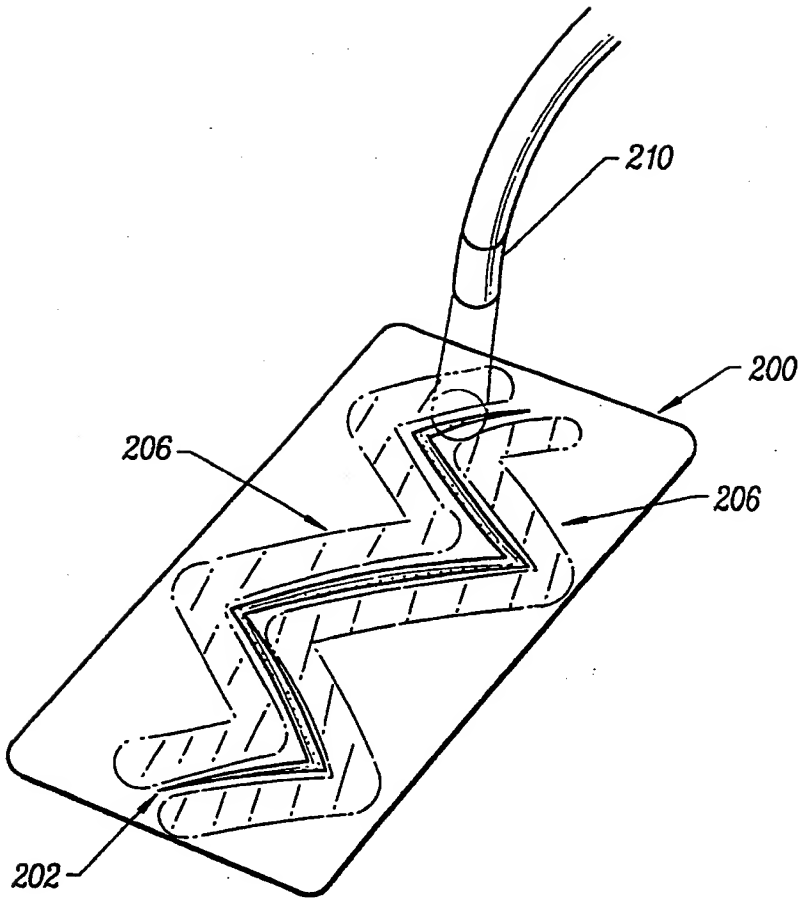


FIG. 2B

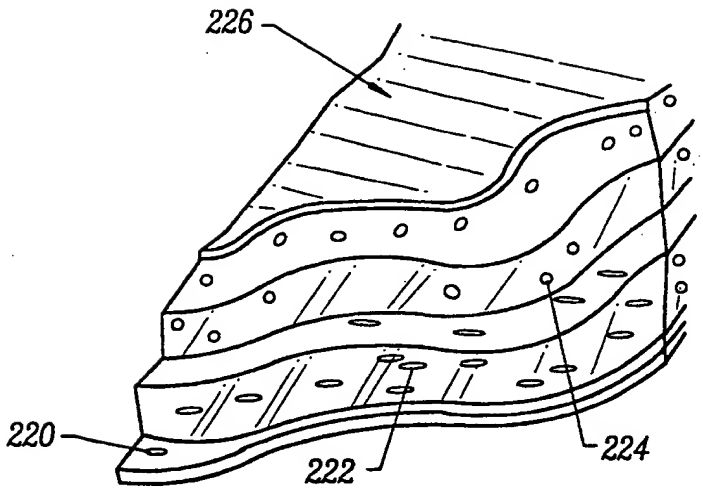


FIG. 2C

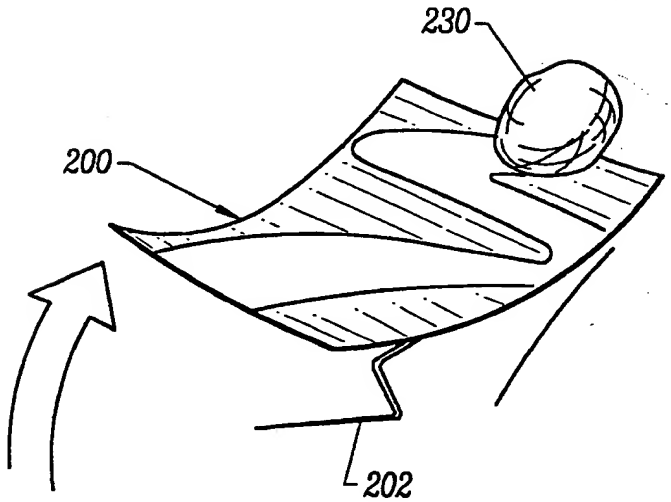


FIG. 2D

INTERNATIONAL SEARCH REPORT

Int. Jonal Application No
PCT/US 97/23588

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/08 A61F13/02

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 4 646 731 A (BROWER) 3 March 1987 see column 2, line 29 - line 49	21 1
A	US 3 786 806 A (JOHNSON) 22 January 1974 see abstract; figures 3,4	1,21
A	WO 95 04511 A (SMITH) 16 February 1995 see page 9	1,21

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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1

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7 April 1998	20/04/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Barton, S

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. ional Application No
PCT/US 97/23588

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4646731 A	03-03-87	NONE	
US 3786806 A	22-01-74	NONE	
WO 9504511 A	16-02-95	AU 7009994 A	28-02-95

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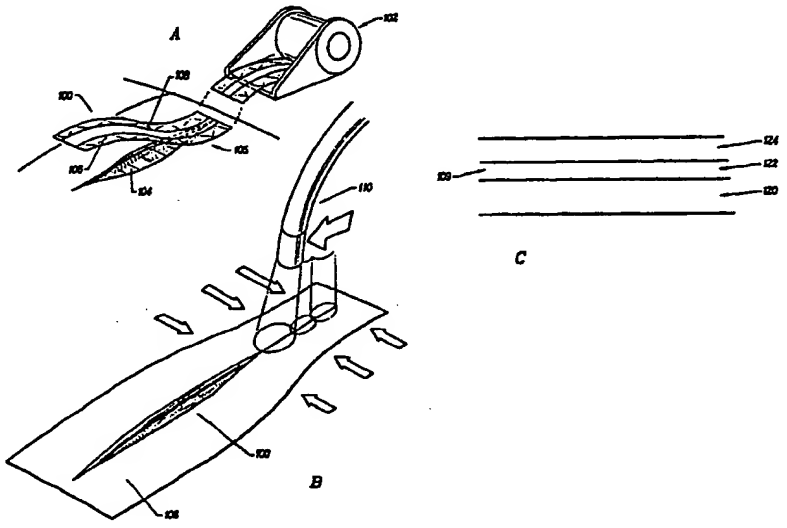
(54) Title: WOUND CLOSURE STRIPS



(57) Abstract

A wound closure strip provides inward tension on the skin from both sides of an incision or wound. The tension is communicated to the skin through the action of an adhesive. Tension is applied by disposing a uniaxially oriented rectangular film or an elastic film support member of the closure strip across the incision. The film then relaxes back to a predefined size (length and width). If the length to width ratio is small, a biaxially oriented film, such as a shrink wrap film, may be used, which is caused to relax to provide the desired force and inward tension across the wound or incision. The wound closure strip may also be a wound healing patch which includes an adhesive trail positioned on a side of the patch that makes contact with the skin. The adhesive trail can be customized or applied so that substantially none of the adhesive covers the wound. Instead, the adhesive trail is positioned adjacent to the wound. The adhesive trail can be activated by a variety of different methods including but not limited to light and pressure.

*(Referred to in PCT Gazette No. 38/1998, Section II)

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